

REMARKS/ARGUMENTS

The present application has been carefully reviewed in light of the September 17, 2004 Office Action. On December 17, 2004, Applicants, their attorney and the Examiner conducted a telephonic conference. In light of the Office Action and the Telephonic Conference, Applicants have amended claims 1, 2, 7 and 11, and added new claims 12-16. Applicants respectfully request reexamination and reconsideration of the application, as amended, and in light of the following remarks.

TIME EXTENSION REQUEST

Applicants submit herewith a one-month time extension request, with appropriate fee.

CLAIM REJECTIONS

All of the originally-filed claims 1-11 were rejected by Okada et al. (U.S. Patent No. 4,323,326). In particular, claims 1-3 and 7 were rejected under 35 USC §102(b) as being anticipated by the Okada et al. reference. The remaining claims 4-6 and 8-11 were rejected as being unpatentable over 35 USC §103(a) over Okada et al.

In the aforementioned telephone conference with the Examiner, Applicant argued that Okada et al. does not disclose a flat cutting edge at the tip of the screw. The Examiner asserted that in fact Okada et al. disclose two flat cutting edges (8 and 9). In response, Applicants have amended the independent claims (1, 7 and 11) to specifically recite that the tip of the body defines a single generally flat cutting edge of an opposite end thereof which is disposed generally perpendicular to a central longitudinal axis of the body. Applicants respectfully submit that Okada et al. simply does not disclose such structure. Instead, Okada et al. in column 2, lines 26-29 (referring to FIG. 1A) specifically state that their tip is a conical angle tip ranging between 90°-120°. Essentially, the cutting edges 8 and 9 of Okada et al. taper to a point, which is typical with screws. In contrast, as disclosed in the present Specification and drawings, the present invention has a single flat cutting edge at its tip. As discussed in the Specification on page 3, last full paragraph, the flat

cutting edge of the present invention avoids “the wobbling” when the surgeon attempts to start the screw into the bone, and thus providing a stable start into the bone and creating a knife effect. The flat cutting edge also remains sharp, allowing for multiple removal for insertion of the same screw.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. M.P.E.P. §2143.03 (citing In re Royka, 180 USPQ 580 (CCPA 1974)). All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 165 USPQ 494, 496 (CCPA 1970)). Given the additional recitations providing clarity to the “flat cutting edge” of the original independent claims, Applicants respectfully assert that, as amended, when all of the claim limitations are considered the Okada et al. reference fails to either anticipate or render obvious the claimed invention. Accordingly, Applicants respectfully assert that independent claims 1, 7 and 11 and thus their dependent claims) are patentably distinct from the Okada et al. reference.

Claims 2, 7 and 11 recite that the dual lead thread of the screw of the present application is variable pitched. Okada et al. make no specific claim or reference to variable or multi-pitched threads. In the Telephone Conference, the Examiner pointed to figure 1B for the proposition that Okada et al. indeed teach a variable or multi-pitched thread. However, Applicants respectfully assert that the functionality of this implied variable pitched thread is a drafting discrepancy because of the angle to the thread to the center axis of the screw create such an extreme acute angle that provide no functionality of the common thread design (which is implied due to lack of statements otherwise in the Okada et al. reference). Instead, the illustration in FIG. 1B shows an extreme version of the forward tapering portion of the inner-shank, and not a variable thread pitch. Applicant believes this is clear by examining FIG. 1B wherein the thread of cutting edge 8 wraps around to point 7, wherein the thread of cutting edge 9 wraps around to point 6. Applicants respectfully assert that one of ordinary skill in the art will conclude that Okada et al. threads are a constant pitch design. Thus, Applicants respectfully assert that claims 2, 7

and 11 are patentably distinct from Okada et al. for claiming that the dual lead thread is variable or pitched.

Claims 7 and 12 recite that the dual lead thread extends from the tip to the head. The dual lead thread of Okada et al. terminates at point 6A of FIG. 1B, as described in column 21, lines 10-14. Column 2, lines 23-26 restate that the thread terminate at point 6A as well. This termination results in a single thread for the remainder of the shank up to the head. Thus, Okada, et al. fail to disclose a dual lead thread extending continuously from the tip to the head.

Claim 11 has been amended to recite that the body has a generally constant root diameter (as also recited in new claims 13 and 15). This is evident from FIGS. 1, 2 and 4 of the present application. In contrast, Okada, et al. disclose a variable root diameter as discussed in column 2, lines 43-80, and column 4, lines 46-54, and FIGS. 4 and 5.

Applicants also amended claim 11 to recite that the dual lead thread has a normal rake angle (also recited in new claims 14 and 16). This is evidenced from FIGS. 1 and 2 from the current specification. Applicants respectfully assert that one of ordinary skill in the art would readily appreciate this aspect given the drawings. In contrast, Okada et al. discloses a negative rake angle, which is non-standard or not normal.

As stated by M.P.E.P. §2141.02, in determining the differences between the prior art and the claims, the question under 35 USC §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. Citing, Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 871 (Fed. Cir. 1983); Schenck v. Norton Corp., 218 USPQ 698 (Fed. Cir. 1983). Further, a prior art reference must be considered in its entirety, i.e., as a whole including portions that would lead away from the claimed invention. M.P.E.P. §2141.02, citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303 (Fed. Cir. 1983), cert. Denied, 469 US 851 (1984).

The present invention is concerned with a self-drilling, self-tapping bone screw having a single flat cutting tip to provide a stable start into the bone and create a knife-cutting effect which remains sharp for allowing

multiple removal and insertion of the same screw. The double-lead thread design, which is variable pitched, not only provides an easy start of the screw into the bone, but also facilitates drilling into the bone, resulting in double the axial travel per turn and results in pulling bone chips out of the hole instead of compressing the bone chips inside the hole.

Okada et al. is directed to a self-drilling screw for use in fastening together steel sheets of large thickness (col. 1, lns. 15-20). Okada et al. disclose a cutting tip having a conical point, a dual thread design extending only partially up the shank and does not disclose a variable pitch thread design.

Thus, Applicants assert, when considering the reference as a whole, the Okada et al. reference actually leads away from the claimed invention and does not anticipate or render it obvious, particularly in light of the current claim amendments. Moreover, Okada et al. do not discuss whatsoever the problems solved by the present invention.

In the rare case where the prior art does not appreciate the existence of the problem solved by the invention, the applicant's recognition of the problem is, in itself, strong evidence of the non-obviousness of the invention. In re Nomiya et al., 184 USPQ 607, 612-613 (CCPA 1975).

CONCLUSION

In light of the foregoing amendments and remarks, Applicants respectfully assert that claims 1-16 of the present application are patentably distinct from the Okada et al. reference and in condition for allowance, notice of which is hereby respectfully requested.

Respectfully submitted,

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